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# Book Review: "In Vitro Drug Release Testing of Special Dosage Forms," Advances in Pharmaceutical Technology Series, Edited by Fotaki and Klein

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The latest addition to the Advances in Pharmaceutical Technology Series entitled *In Vitro Drug Release Testing of Special Dosage Forms* (Fotaki, N.; Klein, S.; Eds., John Wiley and Sons, 2020. ISBN 9781118341476) is a fascinating book that charts the performance testing of special dosage forms, beginning with more unusual oral dosage forms (lipid based and chewable products) and moving on to a wide variety of non-oral products, including injections, stents, topicals, inhalation products, suppositories, and ophthalmic products. This book concludes with a superb chapter on compendial, regulatory, and guidance documents related to in vitro release testing. The chapters discuss the unique needs for each dosage form, typical characteristics of the drug product, and in vitro testing techniques. The book is informative and interesting to read, including over 750 references to recent literature, providing the reader with quick access to thought leaders in the various arenas and reference to pertinent publications.

The first section of the book discusses oral dosage forms beyond the traditional tablets and capsules, addressing lipid-based dosage forms (which are critical in today's environment, where most drugs have poor water solubility) and chewable products (tablets, gums, and soft gel capsules). Case studies are included, providing practical application of in vitro release tests with compendial or regulatory expectations.

Most of the book is devoted to non-oral dosage forms. Although oral products may be the most common dosage form, and perhaps the easiest to administer, other routes of administration are required for some medical conditions. For example, injections may be employed to avoid the harsh conditions of the stomach or to avoid first pass effects in the liver. An entire chapter is focused on this approach, including rationale, in vitro testing considerations, and in vitro-in vivo correlations. A chapter on drug-eluting stents is educational from a technical perspective on the stents themselves and their mechanisms, and addresses apparatus requirements, which are much different from traditional dissolution testing methods.

Inhalation products serve an important function for the patients who use them, and consistent delivery of drugs to the lungs is a critical characteristic. This led to the development of the Anderson Cascade Impactor, and more recently, several other devices designed to evaluate the reproducibility of the dosage forms. The chapter also includes an interesting section on simulating lung fluids.

Topical and transdermal dosage forms address the largest organ of the body: the skin. Understanding drug release from these products is challenging; it is even more challenging to demonstrate this by in vitro testing. Several adaptations of traditional compendial dissolution apparatus have been used for this purpose, and these are discussed in the chapter on topicals and transdermals.

Other orifices in the body have been used for drug introduction, including the vagina, rectum, and eyes. The book includes chapters on each of these approaches, including cases studies and apparatus designed to address the unique aspects of these dosage forms.

The book concludes with a comprehensive review of regulatory considerations related to in vitro release testing of dosage forms. Part one discusses the current state of compendial recommendations including USP, EP, and JP, and guidances from FDA, EMA, Japan's NIHS, ICH, FIP, and WHO. Part two addresses the role of method development in setting clinically relevant specifications - an intriguing and challenging topic.

Overall, *In Vitro Drug Release Testing of Special Dosage Forms* is an excellent resource for those working with dosage forms that go beyond conventional tablets and capsules. It provides excellent background regarding the requirements for these special dosage forms, some information about how dosage forms have been designed, and real-life case studies on how in vitro release testing has been addressed. The extensive list of references for each chapter assists the reader in identifying thought leaders for the different types of special dosage forms. This book is recommended for anyone interested in in vitro release testing and is a fine reference for those who need to develop tests for these special dosage forms.